

The effects of homocysteine-lowering vitamin supplementation on migraine disability

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
29/11/2007	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
18/12/2007	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
18/12/2007	Nervous System Diseases	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

Does vitamin therapy including folic acid reduce homocysteine and migraine disability, and is the effect dependent on MTHFR genotype?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Griffith University Ethics Committee on 11 November 2005 (ref: 3425)

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Migraine with aura

Interventions

Daily B vitamin (B6, B9, B12) therapy vs placebo for 6 months

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Migraine disability, as measured using the Migraine Disability Assessment (MIDAS) score at baseline and 6 months.

Key secondary outcome(s)

1. Migraine frequency. Duration of follow-up: 6 months
2. Migraine pain: MIDAS pain score 1-10 (10 = most severe) at baseline and 6 months

Completion date

30/11/2007

Eligibility

Key inclusion criteria

1. Current diagnosis of regular migraine with aura attacks
2. >18 and <70 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Co-morbid vascular or neuropsychiatric disease
2. Pregnant
3. Currently taking B vitamins

Date of first enrolment

30/11/2006

Date of final enrolment

30/11/2007

Locations

Countries of recruitment

Australia

Study participating centre

Griffith University

Gold Coast

Australia

9726

Sponsor information

Organisation

Griffith University (Australia)

ROR

<https://ror.org/02sc3r913>

Funder(s)

Funder type

Research organisation

Funder Name

Brain Foundation of Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration